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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,564	02/26/2002	Keith K. Dacllenbach	BJT 332	8968

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EXAMINER	
SCHELL, LAURA C	
ART UNIT	PAPER NUMBER
3767	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/085,564	DAELLENBACH, KEITH K.	
	Examiner	Art Unit	
	Laura C. Schell	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 33-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 33-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/23/05-4/13/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9, 14, 15 and 33-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Nash et al. (US Patent No. 6,709,427). Nash discloses a needle-free jet injection device (Fig. 7) for delivering a fluid into an internal organ (1), the device comprising: a rigid end effector (204; col. 23, lines 13-16) having a longitudinal axis configured into a shape and including a plurality of orifices (212), the end effector including a rigid interior wall (interior of 204) that defines a rigid fluid channel (208), where the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use (col. 23, lines 13-16), where the fluid channel has a cross-section through which a central axis of the end effector extends (Fig. 7), and where the end effector is configured to enable fluid to flow from the fluid channel out through the plurality of orifices (fig. 7); a fluid reservoir (72) in fluid communication with the end effector; and an ejection mechanism (214) adapted to eject the fluid from the fluid reservoir through the end effector and out of the orifices with sufficient pressure to penetrate the organ while

preserving functionality of the organ (col. 24, lines 18-24), where the end effector extends away from the ejection mechanism such that an operative end of the end effector is spaced from the ejection mechanism (Fig. 7).

In reference to claim 2, Nash discloses that the end effector includes a straight shaft section (near 204) and a distal section (near 212).

In reference to claim 3, Nash discloses that at least some of the orifices are located in the distal section (orifices 212 are located in the distal section).

In reference to claim 4, Nash discloses that all of the orifices are located in the distal section (orifices 212 are located in the distal section).

In reference to claim 5, Nash discloses that the ejection mechanism is further adapted to allow the device to eject multiple doses of fluid without refilling the fluid reservoir (col. 24, lines 29-31).

In reference to claims 6 and 7, Nash discloses that the pressure with which the fluid is ejected through the orifice is sufficient to cause a transmural lesion in the organ and that the organ is the heart (col. 2, line 18).

In reference to claim 9, Nash discloses that the transmural lesion is sufficient to prevent electrical signals from traveling through the transmural lesion (col. 15, lines 38-40).

In reference to claims 14 and 15, Nash discloses that the distal section lies at an angle between 30 and 90 degrees relative to the shaft, more specifically at an angle of 45 degrees (Figs. 9 and 10).

In reference to claim 33, Nash discloses that the fluid channel is cylindrical (Fig. 7).

In reference to claim 34, Nash discloses that the distal end of the end effector includes a blunt distal end (Fig. 8).

In reference to claims 35 and 36, Nash discloses that all of the orifices (212) are oriented in a direction generally lateral to the central axis of the end effector (Fig. 7).

Claims 19, 20 and 40-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Nash et al. (US Patent No. 6,709,427). Nash discloses an end effector for a needle-free injection device (Fig. 7) adapted to inject a fluid into an internal organ while maintaining functionality of the organ (col. 23, lines 13-16), the end effector comprising a longitudinally rigid elongate shaft (204) that extends away from the injection device and that includes a tubular fluid channel (208) fluidly and directly coupled with a plurality of orifices (212) through which the fluid may be ejected, wherein the elongate shaft is sufficiently rigid to maintain a longitudinal shape during use (col. 23, lines 13-16), where the tubular fluid channel has a cross-section through which a central axis of the end effector extends, and where the tubular fluid channel includes a rigid portion (208) extending substantially all the way between the injection device and the plurality of orifices.

In reference to claim 20, Nash discloses that the end effector includes a straight section (near 204) and a distal section (near 212).

In reference to claim 40, Nash discloses that the longitudinal axis of the distal section is collinear with the longitudinal axis of the straight shaft section (Fig. 7).

In reference to claim 41, Nash discloses that at least a portion of the longitudinal axis of the distal section is not collinear with a longitudinal axis of the straight shaft section (Figs. 9 and 10).

In reference to claims 42 and 43, Nash discloses that the distal section lies at an angle between 30 and 90 degrees relative to the shaft, more specifically at an angle of 45 degrees (Figs. 9 and 10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (US Patent No. 6,709,427) in view of Glines et al. (US Patent No. 6,716,190). Nash discloses the device substantially as claimed, except for the device ejecting ethanol. Glines, however, discloses a needle-free jet injection device which delivers ethanol (col. 18, lines 29-32). Therefore it would have been obvious to one of ordinary skill in the art to have used the needle-free jet injection device of Nash to deliver ethanol, as taught by Glines, because ethanol is fluid that is particularly useful to inject into tissues, particularly to ablate a tissue at the site of the jet injector.

Claims 10-13 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (US Patent No. 6,709,427). Nash discloses the device substantially as claimed including that the device is capable of generating pressures of several thousand psi (col. 24, lines 18-23). Nash, however, does not disclose the specific pressures of less than 4000, 2100 or 1100 psig nor the specific dimensions of the device, such as specific lengths and diameters of parts. It would have been obvious to one of ordinary skill in the art to eject fluid from the device at pressures less than 4000, 2100 or 1100 psig, and the claimed lengths and diameters since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 16-18 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (US Patent No. 6,709,427) in view of Paskar (US Patent

No. 6,623,449). Nash discloses the device substantially as claimed including orifices on the end effector (Fig. 7, 212). Nash further discloses that all of the orifices are located in the distal section (Fig. 7). Nash also discloses that the distal section is curved and angled relative to the straight section (Figs. 9 and 10). However, Nash does not disclose that the orifices are arranged along the length of the end effector or how they are arranged in rows. Paskar, however, discloses an end effector (Fig. 16) which has orifices (134) arranged in multiple offset rows along the length of the end effector. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Nash's end effector with the arrangement of orifices, as taught by Paskar, in order to provide a device which could be used to cover and treat more area of the tissue and thus provide a faster and more efficient treatment.

Response to Arguments

Applicant's arguments with respect to claims 1-25, 33-43 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons